UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement Therapy Products Liability Litigation	MDL No. 2545 Case No. 14-cv-1748 Honorable Matthew F. Kennelly
Daniel Licon, Plaintiff, v. Auxilium Pharmaceuticals, Inc. Defendant.	COMPLAINT AND DEMAND FOR JURY TRIAL Case No. 1:14-cv-8602

COMPLAINT

Plaintiff, Daniel Licon, an individual, complaining against Defendant, Auxilium Pharmaceuticals, Inc., states as follows:

I. PROCEDURAL AND FACTUAL BACKGROUND

A. INTRODUCTION

1. This case involves the prescription drug Testim, manufactured, sold, distributed and promoted by Defendant Auxilium Pharmaceuticals, Inc. (hereinafter "Defendant") as a testosterone replacement therapy.

2. Defendant misrepresented that Testim is a safe and effective treatment for hypogonadism and a condition it referred to as "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thromboembolic events.

3. Testim causes an increase in hematocrit and estradiol in adult males, resulting in thickened blood, the development of blood clots, and heart damage. This effect, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries.

4. Defendant failed to adequately warn physicians about the risks associated with Testim and the monitoring required to ensure their patients' safety.

5. Defendant engaged in aggressive, award-winning direct-to-consumer and physician marketing and advertising campaigns for Testim. Further, Defendant engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "Low T", an abbreviated term for low testosterone.

6. According to the industry-leading Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include being "sad or grumpy," "experiencing deterioration in the ability to play sports," and "falling asleep after dinner." *Available at*: http://www.isitlowt.com/do-you-have-low-t/low-t-quiz. Most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural aging process.

7. The FDA has not approved any testosterone replacement therapy drug as a treatment for "low testosterone." Additionally, "low testosterone" is not a disease recognized by the medical community.

8. As a result of this "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, diagnoses of "Low T" have increased exponentially, resulting in a huge increase in sales of testosterone replacement therapies like Testim.

9. Consumers of Testim relied on Defendant's false representations and were misled as to the drug's safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thromboembolic events.

B. PARTIES

10. Plaintiff Daniel Licon is and was at all times relevant hereto, a resident of Pittsburg, Contra Costa County, California.

11. Defendant Auxilium Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 640 Lee Road, Chesterbrook, Pennsylvania 19087.

C. JURISDICTION AND VENUE

12. Subject matter of this action arises under 28 U.S.C. § 1332. The parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

13. This Court has personal jurisdiction over Defendants because Defendants have significant contacts with the State of Illinois.

14. Venue is proper in this judicial district pursuant to the Order issued by the United States Judicial Panel on Multidistrict Litigation on June 6, 2014, establishing MDL No. 2545 and consolidating for pre-trial purposes all cases involving injuries arising from the use of testosterone replacement therapies before the Honorable Matthew F. Kennelly in the Northern District of Illinois.

15. Plaintiff states that but for the Order consolidating all testosterone replacement therapies before the Honorable Matthew F. Kennelly in the Northern District of Illinois, Plaintiff would have filed in the United States District Court, Northern District of California. Therefore,

Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the above referenced District Court.

D. FACTUAL BACKGROUND

1. General Allegations

16. This action is for damages brought on behalf of the Plaintiff Daniel Licon, who was prescribed and supplied with, received and who has taken and applied the prescription drug Testim, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendant. This action seeks, among other relief, general and special damages and equitable relief in order to enable the Plaintiff Daniel Licon to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

17. Defendant's wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

18. At all times herein mentioned, Defendant was engaged in the business of, or was a successor in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Testim for the use and application by men, including, but not limited to, Plaintiff Daniel Licon.

19. At all times herein mentioned, Defendant was authorized to do business within the states of California and Illinois.

20. At all times herein mentioned, the officers and directors of Defendant participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

21. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drug caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendant herein misrepresented and continues to misrepresent to the public and to the medical profession that the drug Testim is safe and free from serious side effects, and Defendant fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

2. Regulatory History and Approved Uses

22. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

23. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

24. In men, testosterone levels normally begin a gradual decline after the age of thirty.

25. The average testosterone levels for most men range from 300 to 1,000 ng/dl of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who may have testosterone levels below 300 ng/dl on one day will have normal testosterone levels the next. Additionally, testosterone levels gradually decline as men age. This decline in serum testosterone levels is a normal process that does not represent a medical condition or disease.

26. The Food and Drug Administration approved Testim on October 31, 2002, for the treatment of adult males who have low or no testosterone (hypogonadism) in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

27. Hypogonadism is a specific and recognized condition of the endocrine system, which in men may involve the severely diminished production or nonproduction of testosterone.

28. In 1999, Unimed Pharmaceuticals Inc., a previous manufacturer of testosterone replacement therapies, asserted that hypogonadism was estimated to affect approximately "one million American men." By 2000, the number had apparently increased from one million men to "four to five million American men." By 2003, the number again increased to "up to 20 million men."

29. However, a study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001 - 2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

3. Direct to Consumer Marketing for Unbranded/Off-Label Use

30. Defendant coordinated a massive advertising campaign targeted toward men who did not have hypogonadism, nor had low or no testosterone in conjunction with an associated medical condition. The direct to consumer marketing was designed to convince men that they suffered from a non-existent and unrecognized medical condition called “Low T”, which was a term for low testosterone. Defendant orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential Testim users, and online media including the unbranded website "IsItLowT.com."

31. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These “symptoms” include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

32. Defendant’s national education campaign included the creation and continued operation of the website www.IsItLowT.com. The website asserts that millions of otherwise healthy men experience low testosterone and encourages male visitors to "Take the 'Is it Low T' Quiz." The "Is it Low T" quiz asks men if they have experienced potential signs of low testosterone, including "Have you experienced a recent deterioration in your ability to play sports?", "Are you falling asleep after dinner?", “Are you sad and/or grumpy?”, and “Do you have a lack of energy?”

33. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis University School of Medicine, developed this quiz at the behest of Dutch pharmaceutical company Organon BioSciences, in exchange for a $40,000 grant to his university. The pharmaceutical company instructed Dr. Morley, "Don't make it too long and make it somewhat sexy." Dr. Morley drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morley admits that he has "no trouble calling it a crappy questionnaire" and that it is "not ideal." This is the "Low T Quiz" used on the "IsItLowT" website. Natasha Singer, *Selling that New-Man Feeling*, Nov. 23, 2013, N.Y. TIMES.

34. Defendant has also sought to convince primary care physicians that hypogonadism is synonymous with "Low T," that low testosterone levels are widely under-diagnosed, and that normal and common conditions associated with normal aging could be caused by low testosterone levels.

35. While running its disease awareness campaigns, Defendant promoted its product Testim as an easy-to-use topical testosterone replacement therapy. Defendant contrasted its product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

36. Defendant convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendant's promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

37. Defendant manufactured, sold and promoted Testim to treat a non-existent medical condition that it called "Low T," which was a name it created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, Defendant marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

38. Defendant successfully created a robust and previously nonexistent market for its drug. The company also spent millions on its unbranded marketing including commercials and its websites, www.IsItLowT.com and www.DriveForFive.com, sites which recommend that men have regular checkups with their physicians and five regular tests done: including cholesterol, blood pressure, blood sugar, prostate-specific antigen, and testosterone.

39. Defendant's marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of Testim is safe for human use, even though Defendant knew these claim to be false, and even though Defendant had no reasonable grounds to believe them to be true.

40. Defendant's advertising paid off, as sales of replacement therapies have more than doubled since 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra?*, May 10, 2012, Bloomberg Businessweek, *available at:* http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

4. Adverse Events and Serious Health Risks Caused by TRT.

41. There have been a number of studies associating testosterone use in men with an increased risk of serious injuries from blood clots and cardiovascular events.

42. Testosterone replacement therapy involves the administration of exogenous testosterone into the male body in an attempt to raise the serum level of total testosterone. This is achieved through the application of a cream, gel or patch directly to the skin for transdermal absorption into the body. It can also be delivered into the body by subcutaneous injection or placement of a time-released pellet containing the drug.

43. The absorption of exogenous testosterone into the male body can cause an increase in serum levels of testosterone, and it also results in an increase in hematocrit[1] and serum estradiol levels[2].

44. Hematocrit is the proportion of total blood volume that is comprised of red blood cells. Erythrocytosis is an increase in the number of circulating red blood cells especially resulting from a known stimulus (like testosterone). When a person's hematocrit level is raised through erythrocytosis, the resulting condition is called polycythemia, which simply means an elevated red blood cell count. The range for normal hematocrit levels in adult males is 44%-48%.

45. The administration of exogenous testosterone causes a 7%-10% increase in hematocrit levels in adult males through the process of erythrocytosis.[3] An increase of hematocrit that is 7%-10% above normal range is a significant elevation and qualifies as polycythemia. This is a serious medical condition that requires treatment to prevent injury.

46. The clinical trial data submitted to the FDA for the approval of AndroGel, another popular testosterone therapy, showed that the use of exogenous testosterone resulted in nine percent of subjects experiencing hematocrit levels greater than 56% at some point during the

[1] Fernandez-Balsells, M., et al., Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis. J Clin Endocrinol Metab, June 2010, 95(6):2560–2575.
[2] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.
[3] Bachman, E., et al. Testosterone Induces Erythrocytosis via Increased Erythropoietin and Suppressed Hepcidin: Evidence for a New Erythropoietin/Hemoglobin Set Point. J Gerontol A Biol Sci Med Sci., 2013.

study. A hematocrit level of 56% is significantly elevated above the normal range and qualifies as polycythemia. This is a level that puts the patient at serious risk for an adverse health consequence and requires immediate treatment and/or cessation of the testosterone therapy.

47. Elevated hematocrit is an independent risk factor for stroke and it interacts synergistically with elevated blood pressure. In a published study[4] the cohort for men with a hematocrit level greater than or equal to 51% had a more than doubling of the risk of stroke (RR=2.5), and among males in the cohort who were also hypertensive there was a nine-fold increase in the risk of stroke for those with hematocrit greater than or equal to 51%.

48. Elevated hematocrit is also an independent risk factor for adverse cardiovascular events. Using data from the Framingham Heart Study, researchers documented a strong, graded relationship between hematocrit level and the risk of developing heart failure. In 3,523 Framingham participants, aged 50-65, who were free of a history of heart failure at baseline and were followed prospectively for up to 20 years, individuals with a hematocrit level greater than or equal to 50% had almost double the risk of new-onset heart failure during follow-up, compared with those with a low hematocrit, even after adjustment for conventional risk factors for heart failure.[5]

49. In another study of 680 males conducted over 28 years in Finland, the data showed that men with a hematocrit level greater than or equal to 50% were 2.4 times more likely to die from coronary heart disease than men with hematocrit levels of less than 50%. Even after

[4] Wannamethee G1, Perry IJ, Shaper AG, Haematocrit, hypertension and risk of stroke. J Intern Med. 1994 Feb;235(2):163-8.

[5] Coglianese, E., et al., Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. Am J Cardiol. Jan 15, 2012; 109(2): 241–245. Published online Oct 12, 2011

adjusting for established coronary risk factors, the increased risk remained 1.8-fold for the higher hematocrit cohort.[6]

50. In yet another large, prospective study[7] in Norway, the data show a hazard ratio of 1.25 per 5% rise in hematocrit. In a category-based analysis, a hematocrit level in the upper 20th percentile was found to be associated with a 1.5-fold increased risk of venous thrombosis, and a 2.4-fold increased risk of unprovoked venous thromboembolism compared to men whose hematocrit was in the lower 40th percentile.

51. An increase in the level of hematocrit also causes an increase in the viscosity of the blood. A 10.99% increase of hematocrit produces an increase of one unit relative viscosity, which means approximately a 20% increase in blood viscosity for a healthy individual.[8] An increase in blood viscosity is a known risk factor for ischemic heart disease[9], and it can cause hypertension as blood pressure increase will be 20% or vasodilation will be 4.66% in radius for the physiologic compensation of 20% increased viscosity. Hypertension is a known cause of atherosclerosis, heart failure, and stroke. Testosterone makes blood thick and viscous, which, in turn, can cause numerous health risks and injuries for patients.

52. The major source of estradiol in men comes from the aromatization of testosterone (endogenous and/or exogenous) to estradiol. When men are given testosterone, either by application of an androgen gel or by injection, some of that testosterone is

[6] Kunnas, T, et al., Hematocrit and the risk of coronary heart disease mortality in the TAMRISK study, a 28-year follow-up. Prev. Med. Volume 49, Issue 1, July 2009, Pages 45–47.

[7] Braekkan SK, Mathiesen EB,et al., Hematocrit and risk of venous thromboembolism in a general population. The Tromso study. Haematologica. 2010 Feb; 95(2):270-5.

[8] Cinar, Y., et al., Effect of hematocrit on blood pressure via hyperviscosity. Am J Hypertens. 1999 Jul;12(7):739-43.

[9] Yarnell, JW, et al., Fibrinogen, viscosity, and white blood cell count are major risk factors for ischemic heart disease. The Caerphilly and Speedwell collaborative heart disease studies. Circulation. 1991 Mar;83(3):836-44.

converted by the body (aromatized) to estradiol.[10] The increase of estradiol is in direct relation to the amount of the dose of exogenous testosterone delivered; the higher the dose of testosterone, the higher the level of serum estradiol.[11]

53. In data gathered from 2,197 men who participated in the Honolulu Aging Study from 1991-1993, and who were followed for thromboembolic and hemorrhagic events until 1998, there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower.[12] This study revealed that estradiol blood levels greater than 34.1 pg/mL resulted in this more than doubling of stroke incidence. As a source of embolism, the authors noted that the prevalence of atrial fibrillation rose significantly from 1.0 to 4.4% from the bottom to the top estradiol quintiles. Atrial fibrillation is a known cause of thrombus formation.

54. If men have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant, then the estradiol can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones.[13]

55. In a study published 2006, blood levels of estradiol were measured in 313 men whose average age was 58. Carotid artery intima-media thickness was measured at baseline and then three years later. After adjusting for other risk factors, men with higher levels of estradiol suffered a worsening thickening of their carotid artery wall. This led the researchers to conclude,

[10] Glueck, CJ, et al., Thrombotic events after starting exogenous testosterone in men with previously undiagnosed familial thrombophilia. Trans. Res. Oct. 2011.
[11] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.
[12] Abbott, RD, et al., Serum Estradiol and Risk of Stroke in Elderly Men. Neurology 2007, 68:563-568.
[13] Glueck, CJ, et al., Testosterone, thrombophilia, thrombosis. Blood Coagulation and Fibrinolysis 2014, 25:00–00.

"circulating estradiol is a predictor of progression of carotid artery intima-media thickness in middle-aged men."[14] These findings of a positive association between serum estradiol levels and intima-media thickening supports the notion that estrogens, besides possibly increasing the risk for thrombosis and thereby cardiovascular events, also have an important impact on atherogenesis in men.

56. In a case control study of men in the Framingham cohort *supra*, serum estradiol levels were significantly increased in subjects with coronary heart disease.[15]

57. Estradiol has a direct effect in the male heart through the regulation of gene expression that it does not in female hearts. This effect results in impaired contractile function of the heart in males with elevated levels of serum estradiol. [16] Impaired contractile function results in numerous cardiovascular injuries and disease.

58. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

59. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels", in which a large cohort of men who used testosterone taken from a database of the Veteran's Administration was compared against a cohort of men who did not use

[14] Tivesten, A., et al., Circulating Estradiol is an Independent Predictor of Progression of Carotid Artery Intima-Media Thickness in Middle-Aged Men, J CLIN ENDOCRINOL METAB, November 2006, 91 (11): 4433-4437.
[15] Phillips GB, Castelli WP, Abbott RD, et al., Association of Hyperestrogenemia and Coronary Heart Disease in Men in the Framingham Cohort, Am J Med, 1983 74:863-869.
[16] Kararigas, G., et al., Transcriptome Characterization of Estrogen-Treated Human Myocardium Identifies Myosin Regulatory Light Chain Interacting Protein as a Sex-Specific Element Influencing Contractile Function, JACC Vol. 59, No. 4, January 24, 2012, 2012:410-7.

testosterone. The data showed that among the cohort who used testosterone, the testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

60. On January 29, 2014, a study was released in PLOS ONE entitled “Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men” which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a comorbid condition.

61. In some patient populations, testosterone use can increase the incidence of adverse events and death by over 500%.

5. Insufficient Warnings and Labeling

62. Defendant’s marketing strategy beginning in 2000 has been to aggressively market and sell its product by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendant knew or should have known to result from use of its product.

63. Defendant successfully marketed Testim by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low T."

64. Defendant’s advertising program, sought to create the image and belief by consumers and their physicians that the use of Testim was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendant knew or should have known these claims to be false, and even though Defendant had no reasonable grounds to believe them to be true.

65. Defendant purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Testim. Defendant deceived potential Testim users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

66. Defendant concealed material relevant information from potential Testim users and minimized user and prescriber concern regarding the safety of Testim.

67. In particular, in the warnings Defendant gives in its commercials, online and print advertisements, Defendant fails to mention any potential risk of cardiac event, stroke, pulmonary embolism or other dangerous side effects related to blood clotting and falsely represents that it adequately tested Testim for all likely side effects. Defendant also fails to warn and instruct regarding the importance of adequate monitoring of hematocrit levels.

68. Testim's warnings and the medication guide contained within the package materials does not warn against stroke, pulmonary embolism, transient ischemic attack, cardiovascular disease, myocardial infarction, coronary heart failure, or any thromboembolic event not related to polycythemia.

69. The warnings and medication guide contained within the package materials instruct patients to tell their healthcare provider the following before initiating use of Testim:

- have breast cancer
- have or might have prostate cancer
- have urinary problems due to an enlarged prostate
- have heart problems
- have kidney or liver problems

• have problems breathing while you sleep (sleep apnea)

• have any other medical conditions

However, it fails to instruct patients to tell their healthcare provider if they have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant. It also fails to instruct patients or physicians to be aware of the presence of comorbid conditions or pre-existing heart disease, which has been proven to double the risk in men under the age of 65 who use testosterone therapy.

70. The warnings and medication guide contained within the package materials do warn that the use of the product may result in increased red blood cell count, but do not instruct physicians or patients that it can increase a red blood cell count to the point that it more than doubles the risk for stroke, pulmonary embolism, ischemic heart disease, coronary heart failure, and myocardial infarction. The warning in regard to red blood cell count does not warn patients that hematocrit levels can rise by as much as 10% above normal range, nor does it warn of the serious and life threatening risks that are associated with a red blood cell count that exceeds 50%.

71. The warnings and medication guide contained within the package materials do warn that use of the product may result in risk of blood clots in the veins, but they specifically limit this warning to “blood clots in the legs” and only warns against blood clots in the legs that form as a result of increased red blood cell count (polycythemia). There is no warning for blood clots in the veins other than “blood clots in the legs”, nor is there any warning of blood clots resulting from causes other than polycythemia. Also, there are no warnings against blood clots

in veins as a consequence of polycythemia could result in pulmonary embolism, or other injuries secondary to the formation of deep vein thrombosis in the legs or other parts of the body.

72. The warnings and medication guide contained within the package materials fail to warn that use of the product may result in elevated levels of estradiol. They do not instruct physicians to monitor estradiol levels, nor do they provide any guidance to physicians or patients regarding the significant health risks associated with elevated levels of serum estradiol in men.

73. The warnings and medication guide contained within the package materials do not warn that use of the product may result in the formation of deep vein thrombosis, pulmonary embolism, stroke, infarction, coronary heart failure, cardiovascular disease, or myocardial infarction caused by elevated levels of estradiol, or any other cause unrelated to polycythemia.

74. The warnings and medication guide contained within the package materials do not offer any warning of the very serious health risks for men over the age of 65 who use testosterone replacement therapy. Instead, the label only states that the manufacturer lacks any information regarding the safety or efficacy of testosterone therapy for men over the age of 65. This absence of a warning fails to adequately advise and instruct patients and their physicians of the very serious health risks caused by the use of testosterone in this patient population, despite the fact that this data has been published and available in the medical community for years.

75. On June 19, 2014, the United States Food & Drug Administration issued a statement requiring manufacturers of testosterone requiring to include a general warning in the drug labeling of all approved testosterone products about the risk of blood clots in the veins. Blood clots in the veins, also known as venous thromboembolism (VTE), include deep vein thrombosis (DVT) and pulmonary embolism (PE). The risk of venous blood clots is already included in the labeling of testosterone products as a possible consequence of polycythemia, an

abnormal increase in the number of red blood cells that sometimes occurs with testosterone treatment. Because there have been post-market reports of venous blood clots unrelated to polycythemia, FDA is requiring a change to drug labeling of all testosterone products to provide a more general warning regarding venous blood clots and to ensure this risk is described consistently in the labeling of all approved testosterone products.

76. As a result of this mandate by the FDA, Defendant has updated its warnings in the medication guide for Testim as of June 2014 as follows: "Blood clots in the legs or lungs. Signs and symptoms of a blood clot in your leg can include leg pain, swelling, or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain." However, it still lacks any warning about the risks of elevated estradiol levels, and it contains no warnings for strokes or cardiovascular injuries.

77. A careful review of the warnings, labeling and instructions provided by Defendant for the use of Testim prior to June 2014, would lead a reasonable physician and/or patient to believe that the only risk associated with the use of the product is an increase in red blood cell count and the possibility of a blood clot in the leg. This is misleading and fails to adequately warn physicians and patients about the numerous, life-threatening health risks associated with use of the drug.

78. As a result of Defendant's advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for Testim. If Plaintiff had known the risks and dangers associated with Testim, Plaintiff would not have taken Testim and consequently would not have been subject to its serious side effects.

///

///

6. Case Specific Facts

79. Plaintiff Daniel Licon was born on June 17, 1954 and is 60 years old. He was prescribed and used Testim for symptoms he and his physician attributed to low testosterone as a result of Defendant's advertisements, promotion, and statements made from sales representatives.

80. After taking multiple doses of Testim, on or about November 8, 2012, Plaintiff Daniel Licon suffered a myocardial infarction, or heart attack, as a direct result of his use of testosterone by the mechanism of injury as described above in Section I. D. 4.

81. The Testim Plaintiff Daniel Licon consumed caused physical and emotional impairment which affected his personal and professional life.

82. Prior to using Testim, Plaintiff Daniel Licon had no history of significant cardiovascular problems.

83. Plaintiff incurred significant medical expenses as a result of the treatment he underwent to treat his heart attack. He will incur future medical expenses, as well as lost wages resulting from being unable to work. His ability to labor and earn money has been impaired, he is at increased risk for future health problems and disability, and he suffered physical pain and mental anguish.

84. There was no warning to Plaintiff or his physician that Testim presented a risk of causing a heart attack.

85. Had Plaintiff Daniel Licon known the true risks associated with the use of testosterone medications, including Testim, he would not have consumed Testim and would not have incurred the injuries or damages he did as a result of his use of Testim.

///

II. CAUSES OF ACTION

Count One – Strict Products Liability – Failure to Warn

86. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

87. Defendant is liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement of Torts 2d.

88. The Testim manufactured and/or supplied by Defendant was defective due to inadequate warnings or instructions because Defendant knew or should have known that the product created significant risks of serious bodily harm to consumers, and it failed to adequately warn consumers and/or their health care providers of such risks.

89. Defendant failed to adequately warn consumers and/or their health care providers that Testim could cause increased hematocrit levels that could cause heart attacks, strokes, pulmonary embolism, cardiovascular events and blood clots.

90. Defendant failed to adequately warn consumers and/or their health care providers that while a patient was taking Testim it was necessary to frequently monitor hematocrit levels to prevent heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots.

91. The Testim manufactured and/or supplied by Defendant was defective due to inadequate post-marketing warnings or instructions because, after Defendant knew or should have known of the risk of serious bodily harm from the use of Testim, Defendant failed to provide an adequate warning to consumers and/or their health care providers of the product.

92. As a direct and proximate result of Plaintiff's reasonably anticipated use of Testim as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of

commerce by Defendant, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

Count Two – Negligence

93. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

94. At all times herein mentioned, Defendant had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Testim.

95. At all times herein mentioned, Defendant negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold Testim and failed to adequately test and warn of the risks and dangers of Testim.

96. Despite the fact that Defendant knew or should have known that Testim caused unreasonable, dangerous side effects, Defendant continued to market Testim to consumers including Plaintiff, when there were safer alternative methods and/or no need to treat conditions such as loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions that Testim marketing materials claim are caused by “Low T”.

97. Defendant knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendant’s failure to exercise ordinary care as described above.

98. Defendant's negligence was a proximate cause of Plaintiff's injuries, harm and economic loss that Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

Count Three – Breach of Implied Warranty

99. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

100. Prior to the time that the aforementioned products were used by the Plaintiff, Defendant impliedly warranted to Plaintiff and Plaintiff's agents and physicians that Testim was of merchantable quality and safe and fit for the use for which it was intended.

101. Specifically, Defendant warranted to Plaintiff that its product was intended to treat a condition called "Low T" and that it was safe and fit for that use, but Defendant failed to disclose that "Low T" is not a recognized medical condition and that its testosterone product was not FDA approved to treat any such condition.

102. Plaintiff was and is unskilled in the research, design and manufacture of medical drugs, including Testim, and reasonably relied entirely on the skill, judgment and implied warranty of Defendant in using Testim. As a result, Plaintiff used Defendant's product as warranted.

103. Testim was neither safe for its intended use nor of merchantable quality, as warranted by Defendant, in that Testim has dangerous propensities when used as intended and will cause severe injuries to users.

104. As a result of the abovementioned breach of implied warranties by Defendant, Plaintiff suffered injuries and damages as alleged herein.

Count Four - Breach of Express Warranty

105. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

106. At all times mentioned, Defendant expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendant or its authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Testim was FDA approved to treat a condition called "Low T", and that it is safe, effective, fit and proper for its intended use. Plaintiff purchased Testim relying upon these warranties.

107. In utilizing Testim, Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Defendant. These warranties and representations were false in that there is no disease or medical condition called "Low T" that is recognized by any medical community, peer-reviewed journal, or learned treatise, and also in that Testim is unsafe and unfit for its purported intended uses.

108. As a result of the abovementioned breach of express warranties by Defendant, Plaintiff suffered injuries and damages as alleged herein.

Count Five - Fraud

109. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

110. Through a sophisticated and well-orchestrated marketing campaign, Defendant set out to invent a fictitious disease/medical condition that it called "Low T," and then purposely

deceived Plaintiff into believing that this was a real disease/medical condition and that Plaintiff suffered from it. Defendant did this through marketing a set of generic and common conditions in middle-aged men, and representing that these conditions were "symptoms" of "Low T." Those commonly occurring conditions were listed in the "Is It LowT Quiz" and included:

- Being tired after dinner
- Diminished ability to play sports
- Lack of energy
- Being sad
- Being grumpy
- Decreased libido

Each of these purported "symptoms" of "Low T" are normal and common conditions for men over the age of 40, and especially common in men over the age of 50.

111. Defendant, from the time it first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Testim, and up to the present, knew that a significant percentage of the subjects in its clinical trial experienced an increase in hematocrit to a level that more than doubled their risk for stroke, heart attack, and clot formation that could result in pulmonary embolism, and as result of published, peer-reviewed medical literature knew that the use of its product could result in a dramatic increase in serum estradiol levels, yet Defendant willfully deceived Plaintiff by concealing from him, Plaintiff's physicians and the general public, the true facts concerning Testim, which Defendant had a duty to disclose.

112. At all times herein mentioned, Defendant conducted a sales and marketing campaign to promote the sale of Testim and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using Testim. Defendant

knew of the foregoing, that Testim is not safe, fit and effective for human consumption, that using Testim is hazardous to health, and that Testim has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

113. Defendant concealed and suppressed the true facts concerning Testim, and the actual disease for which it has been FDA approved to treat (hypogonadism), with the intent to defraud Plaintiff, in that Defendant knew that Plaintiff's physicians would not prescribe Testim, and Plaintiff would not have used Testim, if they were aware of the true facts concerning its dangers.

114. Plaintiff relied on the fraudulent and deceptive representations made by Defendant to his detriment. Specifically, Plaintiff relied on representations that "Low T" was an actual disease that required medical treatment and use of prescription testosterone, that Testim was FDA approved to treat a condition called "Low T", and that Testim was a safe and effective treatment for his "Low T".

115. As a result of Defendant's fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

Count Six – Negligent Misrepresentation

116. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

117. From the time Testim was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendant made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that "Low T" was an actual disease/medical condition for which

medical treatment was indicated, and that Testim was safe, fit, effective, and FDA approved for human consumption to treat "Low T". At all times mentioned, Defendant conducted a sales and marketing campaign to promote the sale of Testim and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

118. Defendant made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by Defendant, by sales representatives and other authorized agents of Defendant, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

119. The representations by Defendant were in fact false, in that Testim is not safe, fit and effective for human consumption, using Testim is hazardous to health, and Testim has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

120. The foregoing representations by Defendant were made with the intention of inducing reliance and the prescription, purchase and use of Testim.

121. Plaintiff relied on the misrepresentations made by Defendant to his detriment. Specifically, Plaintiff relied on representations that "Low T" was an actual disease that required medical treatment and use of prescription testosterone, that Testim was FDA approved to treat a condition called "Low T," and that Testim was a safe and effective treatment for his "Low T."

122. In reliance on the misrepresentations by Defendant, Plaintiff was induced to purchase and use Testim. If Plaintiff had known of the true facts and the facts concealed by Defendant, Plaintiff would not have used Testim. The reliance of Plaintiff upon Defendant's

misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

123. As a result of the foregoing negligent misrepresentations by Defendant, Plaintiff suffered injuries and damages as alleged herein.

Count Seven - Design Defect

124. Defendant participated in the manufacture, sale and marketing of Testim, an exogenous testosterone drug that was FDA approved to treat a specific medical condition called hypogonadism, which is defined as a condition in which a male produces no or very low testosterone in conjunction with an associated medical condition, such as failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

125. Defendant manufactured, sold and promoted the drug to treat a non-existent medical condition that it called "Low T," which was a name it created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, Defendant marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

126. Defendant manufactured, sold, and promoted this drug which contained a defective condition because the design was defective and unsafe in that it caused serious injuries and death as the result of the formation of blood clots and adverse cardiovascular events, including but not limited to deep vein thrombosis, pulmonary embolism, stroke, ischemic injuries, infarctions, coronary heart failure, and cardiovascular disease.

127. This design defect made the drug unreasonably dangerous, yet Defendant knowingly introduced the drug into the market.

128. The drug as manufactured by Defendant remained unchanged and was in the same condition at the time of the injury hereafter alleged.

129. As a direct and proximate cause of Defendant's manufacture, sale and promotion of the defectively designed drug, Plaintiff sustained permanent injury.

Punitive Damages Allegations

130. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

131. The acts, conduct, and omissions of Defendant, as alleged throughout this Complaint were willful and malicious. Defendant committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other Testim users and for the primary purpose of increasing Defendant's profits from the sale and distribution of Testim. Defendant's outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendant in an amount appropriate to punish and make an example of Defendant.

132. Prior to the manufacturing, sale, and distribution of Testim, Defendant knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendant, through its officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendant unreasonably subjected consumers of said drugs to risk of injury or death from using Testim.

133. Despite its knowledge, Defendant, acting through its officers, directors and managing agents for the purpose of enhancing Defendant's profits, knowingly and deliberately

failed to remedy the known defects in Testim and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Testim. Defendant and its agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Testim knowing these actions would expose persons to serious danger in order to advance Defendant's pecuniary interest and monetary profits.

134. Defendant's conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendant with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER

WHEREFORE, Plaintiff prays for judgment against Defendant, as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff:

A. General damages in an amount that will conform to proof at time of trial;

B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

C. Loss of earnings and impaired earning capacity according to proof at the time of trial;

D. Medical expenses, past and future, according to proof at the time of trial;

E. For past and future mental and emotional distress, according to proof;

F. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;

G. For punitive or exemplary damages according to proof;

H. Restitution, disgorgement of profits, and other equitable relief;

I. Injunctive relief;

J. Attorney's fees;

K. For costs of suit incurred herein;

L. For pre-judgment interest as provided by law; and

M. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims so triable in this action.

October 30, 2014 Respectfully Submitted,

/s/ Daniel S. Robinson
Mark P. Robinson, Jr.
Daniel S. Robinson
Wesley K. Polischuk
ROBINSON CALCAGNIE ROBINSON SHAPIRO DAVIS, INC.
19 Corporate Plaza Drive
Newport Beach, CA 92660
Telephone: (949) 720-1288
Facsimile: (949) 720-1292
drobinson@rcrsd.com
wpolischuk@rcrsd.com

Attorneys for Plaintiff